

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**
(PCT Rule 66)

Date of mailing (day/month/year) **16 JUN 2005**

Applicant's or agent's file reference
MERL20401577/SJ/JW/mt

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International application No.
PCT/SG2004/000319

International filing date (day/month/year)
30 September 2004

Priority date (day/month/year)
7 November 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61M 29/00, A61 2/06, A61B 17/12

Applicant

MERLIN MD PTE LTD (et al.)

1. ☒ The written opinion established by the International Searching Authority:

☒ is ☐ is not

considered to be a written opinion of the International Preliminary Examining Authority.

2. This **third** (second, etc.) opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

The applicant is hereby invited to reply to this opinion.

When? See the Reply Due date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the Final Date by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.
Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the Final Date by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

4. The FINAL DATE by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: **7 March 2006**

Name and mailing address of the IPEA/AU
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DUE DATE

16-8-05

REMINDER

16-7-05

15/06 05 11:04 FAX 701 2 02011233 11 AUGUST 2004

WRITTEN OPINION OF THE
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International application No.

PCT/SG2004/000319

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This opinion is based on a translation from the original language into the following language
which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):

- ☐ the international application as originally filed/furnished
- ☒ the description: pages 1-18 , as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of
- ☒ the claims: pages , as originally filed/furnished
pages , as amended (together with any statement) under Article 19,
pages 19-22 , received by this Authority on 02.05.05 with the letter of 22.04.05
pages , received by this Authority on with the letter of
- ☒ the drawings: pages 1/4 -4/4 , as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

WRITTEN OPINION OF THE
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International application No.

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Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 4-18, 24-31	YES
	Claims 1-3, 19-23	NO
Inventive step (IS)	Claims	YES
	Claims 1-31	NO
Industrial applicability (IA)	Claims 1-31	YES
	Claims	NO

Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 2003/0093111 A1
- D2 WO 1998014137 A1
- D3 EP 0947204 A2
- D4 US 6024765 A
- D5 EP 754435 A1
- D6 EP 1391184 A1

The present amended claims define a stent for insertion into bodily vessel for treatment of aneurysm or ischemic diseases, wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy and where the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium. The claims merely require that the platinum:iridium alloy has a particular composition, and that the platinum alloy may not be the alloy.

My interpretation of the claims is the following:

The last technical feature of the claims "where the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium" relates only to the part of the claims which specify only the first type of alloy: platinum:iridium of 5 different types of alloys claimed. Documents D1, D3, D4 relate mainly to one or several of the four remaining types of claimed alloy; the compositions of those four alloys are not defined in claims.

NOVELTY AND INVENTIVE STEP: Claims 1-31

D1 discloses a vaso-occlusive device of metallic wire and methods of this device to treat patients by implanting such devices at the site of abnormal blood flow; the metallic wire can comprise a metal selected from the group consisting of platinum, tungsten, rhenium, rhodium, ruthenium, nickel and alloys thereof {Abstract, Fig. 1A -3B, paragraph [0003] - paragraph [0044]}. Claims 1-3, are not new and do not involve inventive step in view of this document. Claims 4-18, 24-31 do not involve inventive step in view of this documents as all their technical features are common general knowledge of the art.

D2 discloses a radially expandable stent which is formed of fine wire (10), the wire comprises an alloy selected from the group consisting of Pt-Ir with 90 wt % Pt and 10 wt % Ir {entire document. Claims 1-31 are new and involve inventive step in view of this document.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

D3 discloses an endoprosthesis. In preferred embodiment the body structure includes an elongated central cylindrical core and an elongated outer tubular member disposed around the core. One of the first and second materials comprises the core and the other comprises the tubular member. The first material is preferably selected from the group consisting of platinum, iridium, tungsten alloys thereof and any combination thereof {Abstract, Fig. 1-3, paragraph [0008] – paragraph [0012]}. Claims 1-3, 19-23 are not new and do not involve inventive step in view of this document. Claims 4-18, 24-31 do not involve inventive step in view of this documents as all their technical features are common general knowledge of the art.

D4 discloses an implantable vaso-occlusive coil which is implanted using minimally invasive surgical techniques. The material used in constructing a vaso-occlusive member may be any of a wide variety of materials: alloys of metals of Platinum Group, especially platinum, rhodium {entire document}. Claims 1-3, 19-23 are not new and do not involve inventive step in view of this document. Claims 4-18, 24-31 do not involve inventive step in view if this document as all technical features of these claims are common general knowledge of the art.

D5 discloses a vaso-occlusive device with helically wound coil made of Pt, Rh, W or their alloys {entire document}. Claims 1-31 are new and involve inventive step in view of this document.

D6 discloses an expandable multi-layer tubular sructutue useful as a surgical stent which has two or more layers. The different layers can be made from Pt-Ir alloy {entire document}. Claims 1-31 are new and involve inventive step in view of this document.